Message

From: Wozniak, Chris [wozniak.chris@epa.gov]
Sent: 9/12/2016 7:59:03 PM
To: Evdokimov, Evgenij A [Evgenij.Evdokimov@fda.hhs.gov]; Kough, John [Kough.John@epa.gov]; McAllister, Janet C (CDC) [jvm6@cdc.gov]; Mutebi, John-Paul (CDC) [grv0@cdc.gov]
CC: Dass, Brinda [Brinda.Dass@fda.hhs.gov]
Subject: RE: Oxitec's revised protocol review
Attachments: Investigational field protocol V12 JULY2016 final-CAW.pdf

Hi Evgenij,

I had a couple comments on the document, but nothing major in my opinion. They are actually more for those considering the evaluation of the testing after the fact than anything else.

On pages 20 and 31, I pointed out that the potential for application of adulticides on the same day as a release of OX513A seems to me to be an avoidable issue. Coordination with FKMCD would seem to be able to preclude this. If not, then as Oxitec states, as long as the application of any pesticide is equivalently impacting the TA and UCA, then it will not impact their analysis or at least conflate the comparison. How will anyone know that the two areas are impacted the same by pesticide application?

On page 24, PCR analysis of fluorescent samples is discussed (i.e., is it hemizygous or homozygous?). Could the presence of homozygotes be used to estimate the amount of RIDL female release? Just a thought and more for my own edification than anything else. The numbers may be too small to accurately estimate / quantify in any case.

Also on page 24, there may be a % symbol missing – highlighted in yellow.

Thanks for the opportunity to comment!

Chris

From: Evdokimov, Evgenij A [mailto:Evgenij.Evdokimov@fda.hhs.gov]
Sent: Wednesday, September 07, 2016 10:09 AM
To: Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>; McAllister, Janet C (CDC) <jvm6@cdc.gov>; Mutebi, John-Paul (CDC) <grv0@cdc.gov>
Cc: Dass, Brinda <Brinda.Dass@fda.hhs.gov>
Subject: Oxitec's revised protocol review

Dear members of the team,

Attached are the Oxitec's revised trial protocol and our review of this protocol. The revisions in the trial protocol include new language regarding the post-trial monitoring and additional monitoring around the treatment area for dispersal of OX513A. Please provide your edits and comments, if any, and email them back to me by COB September 12 or sooner.

Please let me know if you have any additional questions.

Thank you,

Evgenij

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Evgenij Evdokimov, PhD

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